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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,079	07/11/2006	James Knox Russell	PHUS040020US2	6955

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EXAMINER	
LAVERT, NICOLE F	
ART UNIT	PAPER NUMBER
3762	
MAIL DATE	DELIVERY MODE
04/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,079	RUSSELL ET AL.	
	Examiner	Art Unit	
	NICOLE F. LAVERT	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-13,15,17,25,27-30 and 34* is/are pending in the application.

4a) Of the above claim(s) *23 and 31-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-13,15,17,25,27-30 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Finality of the previous office action sent out on 22 August 2009 has been withdrawn.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. **Claims 9-12 & 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nolan et al. (US 5,404,877) in view of Burton et al. (US 2004/0193068).

Nolan et al. discloses the claimed invention having a physiological monitoring system and apparatus comprising (e.g., col 1, ln 8-15) at least one sensor for detecting a biological signal, and for detecting physical activity of a monitor-wearing patient [e.g., (col 3, ln 28-44) & (col 4, ln 16-19)], a processing means coupled to sensors including an arrhythmia threshold detector [e.g., (col 5, ln 50-62), (col 8, ln 49-54) & (Fig 1, 28)], an activity threshold detector

coupled to said processing means for receiving signals representative of physical activity [e.g., (col 3, ln 32-44) & (col 4, ln 16-19)], a system error detector (e.g., col 9, ln 10-11) and an user interface for communication about the detected biological signal to the patient [e.g., (col 3, ln 28-59) & (col 7, ln 45-51)]. Note that the analyzer as disclosed by Nolan et al. has the capabilities of classifying the detected malfunctions as instantly claimed due to the analyzer communicating to the alarm if a malfunction exists (e.g., col 9, ln 10-22).

Nolan et al. discloses the claimed invention having a physiological monitoring system and apparatus except wherein said system and apparatus further includes at least one or more electrocardiography electrodes and a means for adaptively controlling the communication of the information about the detected biological signal in accordance with a level of the sensed physical activity. Burton et al. teaches that it is known to use a system for monitoring the state of consciousness of human subjects by sensing physiological senses via the use of ECG electrodes {e.g., [0001], [0177] & (Fig 33)}. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system and apparatus as taught by Nolan et al. with the monitoring system utilizing ECG surface electrodes as taught by Burton et al., since such a modification would provide the physiological monitoring system and apparatus with at least one electrocardiography electrode a means for adaptively controlling the communication of the information about the detected biological signal in accordance with a level of the sensed physical activity for providing the predictable results pertaining to utilizing ECG electrodes in order to monitor the consciousness of a patient so as to effectively apply suitable alarm signaling and/or proper treatment for said patient (e.g., Burton, [0001]-[0002]).

4. **Claim 13 & 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nolan et al. (5,404,877) and Burton et al. (2004/0193068) as applied to claims 9-12 & 17above, and further in view of Toda et al. (US 2002/0036446).

Nolan/Burton et al. discloses the claimed invention having a physiological monitoring system and apparatus including a physical activity sensor except wherein said system and apparatus further comprises a transducer including a piezoelectric element. Toda et al. teaches that it is known to use a piezoelectric transducer with a piezoelectric polymer provided with electrodes on its surface [e.g., 0001]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system and apparatus as taught by Nolan/Burton et al. with the piezoelectric transducer as taught by Toda et al., since such a modification would provide the physiological monitoring system and apparatus with a physical activity sensor comprising a transducer including a piezoelectric element for providing the predictable results pertaining to providing a source of an effective excitation of acoustic energy so as to provide an acoustic feedback signal [e.g., Toda, 0001].

5. **Claims 25 & 27-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nolan et al. (US 5,404,877) in view of Burton et al. (US 2004/0193068) and McGrath et al. (US 4,216,462).

Nolan/Burton et al. discloses the claimed invention having a physiological monitoring system except wherein said system further comprises a system monitor which detects system malfunctions and classifies said malfunctions as critical or non-critical wherein an alarm type is based on said classification. McGrath et al. teaches that it is known in the art to use a system for processing, storing, transmitting and/or displaying data relative to a patient's physiological

condition comprising of an automatic self-diagnostics for malfunction within said system in which a processor is programmed to classify specific malfunctions via the use of flag-bit status words to determine a 'LOW' or 'HIGH' error-status, wherein said status words produced by said processor are further utilized to transmit specific alarm types to an external device [e.g., (col 2, ln 28-41 & 58-60) & (col 8, ln 50-68)-(col 9, ln 1-34)]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Nolan/Burton et al. with the system comprising an automatic self-diagnostics to classify malfunctions as taught by McGrath et al., since such a modification would provide the physiological monitoring system with a system monitor which detects system malfunctions and classifies said malfunctions as critical or non-critical wherein an alarm type is based on said classification for providing the predictable results pertaining to utilizing an automatic self-diagnosing system to determine the effective course of action needed for correcting and processing error data (e.g., McGrath, col 9, ln 31-34).

6. **Claim 34** is rejected under 35 U.S.C. 103(a) as being unpatentable over Nolan et al. (US 5,404,877) in view of Burton et al. (US 2004/0193068) and Lidow (US 4,228,806).

Nolan/Burton et al. discloses the claimed invention having a physiological monitoring system and apparatus except wherein said system and apparatus further includes a means for either transmitting and/or inhibiting the transmission of an alert signal based on sensed physical activity of a patient. Lidow teaches that it is known to use a wake-up alarm, which is inhibited while a subject is in a deep-sleep phase, that either actuates and/or inhibits an output alarm based on information pertaining to physiological and/or physical conditions of a patient being monitored, such as a measured pulse rate related to the sleep phase of an individual [e.g., (col 1,

ln 5-7) & (col 2, ln 6-10 & 25-64)]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system and apparatus as taught by Nolan/Burton et al. with the wake-up alarm structure as taught by Lidow, since such a modification would provide the physiological monitoring system and apparatus with a means for either transmitting and/or inhibiting the transmission of an alert signal based on sensed physical activity of a patient for providing the predictable results pertaining to utilizing a combination of monitored physiological and physical conditions to either actuate and/or inhibit a alarm based on the sensed physical activity of a patient (e.g., Lidow, col 2, ln 25-29).

Response to Arguments

7. Applicant's arguments with respect to claims 9-13, 15, 17, 25, 27-29, 30 & 34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (alt. fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Nicole F. LaVert/
Examiner, Art Unit 3762